

## DRAWING AMENDMENT

Please replace the original drawing figures with the 31 sheets of formal drawings submitted herewith, each sheet marked with the legend "Replacement Sheet".

Explanation of Changes: There are no changes to the drawings other than rendering all sheets in formal fashion by a patent draftsman.

## REMARKS

### Drawing objection

The Examiner objected to the drawings as not showing every feature of the invention disclosed in the claims. Applicants request that the objection be removed because the features are shown in the Figures, as indicated below:

1) a carrier having **an upper surface and a lower surface and first and second side regions.**

The carrier 200 is shown in Figures 8-15. The upper surface is shown in the perspective, top and side views of Figures 8, 9, 10, 11 and 12. The lower surface is shown in Figure 15 (bottom view). The first side region or portion 204 is shown in Figure 9 and in the side view of Figure 12 and the opposite side region is shown in Figure 11. See page 8 lines 3-12; page 16 line 24-page 17 line 6.

2) positioning features comprise **voids formed in a rib projecting from the lower surface**, said rib placed between the **first and second side regions**. See Figures 8 and 15, **void 212** formed in the **rib 214** projecting from the lower surface (Figure 15). The rib 214 is placed between the two sides of the carrier as can be appreciated from Figures 8, 15, 11, 12 and 33. See page 18 line 9-21.

### Section 112 Rejection

Claim 3 was rejected under 35 U.S.C. § 112 for lack of clarity due to the recitation of the rib “depending” from the lower surface of the carrier. The claim has

been amended to recite that the rib “projects” from the lower surface – as shown in Figure 8 and 33. Accordingly, the rejection should be withdrawn.

#### Anticipation Rejection

Claims 1-3 and 8 are rejected as lacking novelty over EP 0 896224 (Maes). Applicants request withdrawal of the rejection of claims in view of the present amendments and following remarks.

The Examiner has cited to the incubation carousel of the Maes reference as the “carrier” of the instant invention. The incubation carousel (including the quarter sections or “quads” thereof 670) of Maes receives test sample cards one at a time, rotates about an axis and the cards are ejected from the top of the carousel to a reader and then sent back to the carousel if the reading indicates that sufficient incubation time has not occurred.

Applicants have amended the claims to distinguish from Maes. In particular, the applicants’ carrier has N receiving structures for receiving N test sample devices and N vessel receiving structures for receiving N vessels containing a fluid test sample. Note in the Applicants’ carrier of Figure 8, the carrier 200 includes N structures 206 for receiving vessels (test tubes) containing a fluid test sample and N receiving structures 202 for receiving a test sample device (test card). See also Figure 3B, 7, 27.

In the carousel 604/670 of Maes, only the test sample devices are contained within the carousel 604 and the test tube remain behind in the “boat” 22 after carousel loading occurs. See paragraphs 33, 35 of Maes. Therefore, the carousel of Maes does not read on the carrier of claim 1. The instrument of Maes includes a cutting and sealing station 500 “upstream” of the carousel which cuts the transfer tube connecting the test

tube to the test card. After the tube has been cut the card is sealed and is ready for incubation and reading. The test tubes are not involved in the incubation or reading process because the sample has already been loaded into the card, hence only the cards are loaded into the carousel. See paragraphs 31-32 of Maes for a description of the vacuum loading and sealing process.

Applicants have crafted claim 1 in Jepson format to distinguish over the “carrier” (boat and cassette combination) of the Maes system in that the boat 22 and cassette 26 combination of Maes does not include the position feature recited after the phrase “the improvement comprising . . .”, namely the optical interrupt positioning feature. In the Maes system, the instrument keeps track of the position of the boat and cassette within the instrument by counting the steps (revolutions) in the stepper motors in the position system 100 which cause the paddles to move the boat and cassette over the base of the instrument. The position of the boat and cassette in Maes is sensed indirectly,<sup>1</sup> whereas in the instant invention the positioning features allow the position of the test tubes and cards to be sensed directly.

Since the Maes carousel does not include features for containing vessels (e.g., test tubes) for containing test samples and the boat 22 and cassette 26 of Maes does not include the optical interrupt feature in the improvement part of the claim, Maes does not anticipate claim 1 or claims dependent therefrom. The anticipation rejection should be removed.

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<sup>1</sup> Further explanation of the test sample positioning system in Maes EP 0 896 224 can be found in the U.S. Patents cited at page 5 lines 3-4 of the instant Specification. These patents were previously cited in applicants’ Information Disclosure Statement.

#### Obviousness Rejection of Claims 4-5

Claims 4 and 5 stand rejected as obvious over Maes in view of Clark, U.S. 5,507,410. Applicants respectfully traverse the rejection.

Claim 4 depends from claim 1 and recites that the carrier further comprises “a first portion having a handle and an opposite second portion having a flat panel, said panel for receiving a bar code associated with said carrier.” In the Maes reference, there is no bar code or bar code receiving panel in either the carousel (604) or carousel section 607, or in either the boat 22 or cassette 26 of the test sample positioning system. Rather, the bar codes are applied to the test sample cards and such codes are read by a bar code reader in the instrument. Maes at paragraph 26. There is no need or motivation to modify the Maes reference to include a bar code on the carousel because the carousel is merely a holder for test sample cards, and remains a permanent installation in the machine (except perhaps for removal for cleaning or maintenance), hence the construction of the carousel in four sections, see Maes at paragraph 49. There is also no need or motivation to add a bar code or a panel for containing such a code to the cassette or boat of Maes since the cassette also includes a touch memory button which is programmed with information as to how the cards are loaded. (see, e.g., U.S. 5,897,835 Figure 9 showing openings 78 for receiving the touch memory buttons).

The examiner cites to Clark for a teaching of a carrier containing the panel and bar code, citing to Figures 36-30 of Clark. This is incorrect. In Clark, the bar codes are applied to a skirt (e.g., 624, 645 (Figure 43) or 655 (Figure 44)) of the test tube device not the carrier of Figure 36. The “carrier” 600 in Clark does not have a bar code applied to it; rather the test tube devices (one of which is shown in figure 39 and several others shown

in Figure 43 and 44) include the panel or skirt which contains the bar code. See Clark at col. 52 lines 35-52. Thus, Maes in combination with Clark would suggest at most applying bar codes to the test tubes of Maes, not the carrier in Maes since the carrier (600) of Clark does not include a bar code. Thus, Maes in combination with Clark does not render obvious claim 4.

As to Claim 5, Clark fails to overcome the deficiency of Maes in failing to teach a carrier for both test devices and test sample vessels, which contains the positioning feature as claimed. The applicants concede that the carrier of Maes (Figure 2) includes a cassette 26 which includes structures which hold the test tubes and test cards in registry with each other. However, neither Maes nor Clark teach or suggest the features of independent claim 1. Therefore, the combination fails to render obvious claim 1 and claim 5 is allowable by virtue of claim dependency.

#### Obviousness rejection of claims 6 and 7

The Examiner cites to Maes in combination with Stevens (US 4,582,990) in rejecting claims 6 and 7. Even assuming the alphanumeric numbering convention of Stevens was applied to the cassette 26 or carousel 604 of Maes, the resulting combination fails to suggest that Maes' positioning system should be changed to include the optical interrupt positioning features of claim 1. Stevens' numbering convention does not in any way assist the instrument user or designer in determining precisely whether a given test sample device or test tube is located within the instrument at a particular location (e.g., the location where pipetting, cutting and sealing, or loading into an incubation station should occur). Accordingly, as Stevens fails to overcome the deficiency of Maes as to

claim 1, the rejection should be withdrawn.

#### Obviousness Rejection of Claims 9 and 10

The Examiner rejected claim 9 as obvious over Maes in view of Clark. The applicants request withdrawal of the rejection in view of the following remarks.

Claim 9 is as follows

9. (currently amended) A carrier for holding test sample devices and test tubes during movement of the test sample devices and test tubes through an automated sample testing instrument, comprising:

a body having an upper portion and a lower portion and first and second side portions;

receiving structures in said upper portion for holding up to N test sample devices and up to N test tubes containing test samples, where N is an integer greater than 1;

a portion comprising a handle and an opposite portion having a flat panel for receiving a machine readable indicium; and

N optical interrupt positioning features, each of said positioning features placed in registry with one of said receiving structures, whereby detection of one of said positioning features by a fixed optical interrupt sensor in said sample testing instrument detects the position of the test sample device placed in the receiving structure corresponding to said positioning feature.

The Examiner's analysis of Maes at pages 8-9 of the office action is faulty as in one portion of the analysis the Examiner is apparently citing to Figure 1 for the cassette/boat as being the "carrier" and then also citing to the carousel as being the "carrier" and citing to the optical interrupt features in the carousel. The optical interrupt features in the carousel do not detect anything with respect to the cassette/boat; rather they only serve to detect the position of the slots of the carousel. The analog of the "carrier" of claim 1 in the Maes reference cannot be both the carousel and the cassette/boat, since they are entirely different devices; rather, it is the cassette/boat combination since that is the structure which is designed for "holding test sample devices

during movement of the test sample devices through an automated sample testing instrument” --- the purpose or function recited in the claim preamble.

The claim recites a body with an upper and lower portion and receiving structures in the upper portion and N optical interrupt positioning features placed in registry with one of the receiving structures in the upper portion. In Maes, the optical interrupt features of the carousel are not a part of a body which includes receiving structures which contain features for holding N test tubes and N test sample devices. Rather, as noted above in Maes there are NO test tubes in the carousel. It is not proper to read the applicants carrier onto the carousel of Maes since the Maes carousel does not meet the requirement of claim 1 of requiring receiving structures for both test sample devices and test tubes, and the cassette/boat of Maes does not include N optical interrupt position features as claimed.

Clark does not disclose the positioning features as claimed. Assuming one skilled in the art could somehow incorporate into Maes Clark's teaching of separate test tubes and test tube holders in Figures 36-39, or bar codes applied to individual test tubes, those teachings in combination with Maes utterly fails to teach one skilled in the art how the Maes boat/cassette combination should or could be modified to include the positioning features as recited in claim 9. Accordingly, Maes in combination with Clark do not render claim 9 or dependent claim 10 obvious.

#### Obviousness Rejection of Claims 11 and 12

The Examiner rejects claims 11 and 12 as obvious over Maes in combination with Clark and Stevens. Stevens is cited for the teaching of the alphanumeric indicia. The



remarks above for claims 6 and 7 are applicable here. Even assuming Stevens' numbering technique was applied to Maes, it fails to suggest any modification to the Maes positioning system for the boat/cassette combination since (a) the alphanumeric numbering is not used for positioning and (b) the alphanumeric numbering does not suggest incorporating the optical interrupt positioning features in the carrier in the manner claimed in claim 9. Accordingly, claim 11 and 12 are allowable by virtue of claim dependency from claim 9.

#### Conclusion

All claims are believed to be allowable over the cited art. Favorable action to that end is requested.

McDonnell Boehnen Hulbert & Berghoff LLP

Date: 9/11/07 by: Thomas A. Fairhall  
Thomas A. Fairhall  
Reg. No. 34591

#### CERTIFICATE OF MAILING

The undersigned hereby certifies that the foregoing Amendment is being deposited as first class mail postage prepaid in an envelope addressed to Commissioner for Patents, P.O. Box 1450 Alexandria VA 22313-1450 on this 11 th day of September, 2007.

Thomas A. Fairhall  
Thomas A. Fairhall